UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/244,457	02/04/99	SCHATZBERG A	05490C-02660

HM42/1001

GREGORY P EINHORN
TOWNSEND & TOWNSEND AND CREW
TWO EMBARCADERO CENTER
8TH FLOOR
SAN FRANCISCO CA 94111-3834

EXAMINER	
JARVIS,W	
ART UNIT	**PAPER NUMBER**
1614	4

DATE MAILED: 10/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/244,457	Schatzberg et al
Examiner	**Group Art Unit**
William R. A. Jarvis	1614

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-21* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-21* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Claims 1-14 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 21 have the proviso "that the patient not be suffering from Cushing's Syndrome," but do not mention a patient in the preamble of the claim. This ambiguity would be corrected if claim 1, for example, is amended, "A method of ameliorating psychosis in a patient in need thereof by administering to said patient an amount of a glucocorticoid receptor antagonist effective to ameliorate the psychosis,..." In order to be consistent with the claims 1 and 21 and for the sake of clarity, claim 14 should be similarly amended by adding a host.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravaris (U.S. Patent 4,814,333), van der Lely, Piazza et al, and Behl et al. Ravaris teaches that the lowering of plasma cortisol levels in patients exhibiting hypercortisolemia (i.e. by inhibiting cortisol biosynthesis) is effective at treating depression including major depression with psychotic features; see col. 1, lines 53-56 and col. 6, lines 51-66. Applicant's methods differ in that they require administering to the patient a glucocorticoid receptor antagonist such as mifepristone in order to lower the cortisol levels. However, since it was well-known at the time of applicant's invention that both cortisol synthesis inhibitors and glucocorticoid antagonists have the same effect of reducing cortisol binding to cells, the skilled artisan would have reasonably expected that a glucocorticoid receptor antagonist would also have the effect of treating depression with psychotic features. Van der Lely teaches that mifepristone reversed psychosis in patients by blocking glucocorticoid receptors. Piazza et al suggests that inhibition of endogenous glucocorticoids would be effective at reducing psychotic symptoms in humans. Behl suggests that glucocorticoid receptor antagonists such as mifepristone would be effective at reducing neuronal degeneration in Alzheimer's Disease by reducing the effects of glucocorticoids in the brain, particularly the hippocampus. Clearly, the references in combination suggest that glucocorticoid receptor antagonists such as mifepristone would be effective at ameliorating psychosis in humans. The claimed amounts and dosage regimen are obvious since it is within the skill of the artisan to determine the amount of drug and frequency of administration that provides the therapeutic effect

required by the patient while producing minimal adverse side effects. The claimed modes of administration are clearly obvious since they are conventional in the art.

4. The claimed kit for the amelioration of psychosis is obvious for the reasons *supra*. However, even if the related methods of use were patentable, the kit would not be patentable since the instructional material suggesting the intended use is not given weight in determining patentability. A kit (which is a composition in a box with instructions) is not limited to the intended use (the host may still use the kit for another purpose). Accordingly, the kit is made obvious by prior art teaching any use of a glucocorticoid receptor antagonist or a composition thereof.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William R. A. Jarvis whose telephone number is (703) 308-4613.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

William R. A. Jarvis
Primary Examiner
Art Unit 1614
September 30, 1999